



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of  
Leslie BAUMANN *et al.*  
Serial No. 10/627,994  
Filed: July 28, 2003  
For: Method for Treating Damaged Skin

Group Art Unit 1623  
Examiner Olson

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

1.131 Declaration of Leslie S. Baumann, M.D.

I, Leslie S. Baumann, being duly sworn, depose and say:

1. I am the co-inventor of US Patent Application Serial No. 10/627,994 and submit this declaration pursuant to 37 C.F.R. § 1.131 for consideration by the US Patent and Trademark Office in connection with this application.
2. I am Chief of the Division of Cosmetic Dermatology and a Professor at the University of Miami School of Medicine in Miami, Florida. I am also the head of the University of Miami Cosmetic Center. I received my medical degree from Baylor University in Houston, Texas, and completed my residency in dermatology at the University of Miami School of Medicine.
3. On June 20, 2002, consistent with the requirements of the University of Miami Patent and Copyright Policy, together with my co-inventor, Dr. Esperanza Welsh, I submitted a Confidential Invention Disclosure to the University. (At the time of the invention, Dr. Welsh was a dermatologist pursuing a post-graduate fellowship in cosmetic dermatology at the University of Miami School of Medicine.)
4. In the Invention Disclosure we described our invention as the use of imiquimod cream for a cosmetic purpose – reducing fine lines and clinical wrinkles on aged skin or non-precancerous, normal photodamaged skin. Our invention disclosure was based on

observations that after topical application of imiquimod aged skin or non-precancerous, normal photodamaged skin exhibited fewer fine lines and clinical wrinkles.

5. On August 10, 2002, I received a memorandum from the University electing title to the invention described in Paragraph 4.

6. During the summer and fall of 2002, I treated patients at the University of Miami Cosmetic Center for the cosmetic condition of facial fine lines and clinical wrinkles resulting from photoaging by topical administration of imiquimod. I continued treating patients with imiquimod for facial photoaging in 2003, including as part of a University-approved clinical study, which is more fully-described in Paragraphs 10 and 11 below.

7. Federal and state laws, as well as University policy, protects patient medical information and prevent disclosure of such information without consent of the patient to whom such information pertains or as otherwise permitted by state and federal law. For this reason, copies of patient medical records with my notes indicating treatment of facial photoaging (*i.e.*, fine lines and clinical wrinkles on aged skin and non-precancerous, normal photodamaged skin) with imiquimod are not attached to this declaration.

8. A portion of my medical practice and clinical responsibilities as head of the University of Miami Cosmetic Center involves conducting clinical trials to support FDA approval of new dermatologic agents as well as new indications of agents that are already in use. In certain instances, FDA approval of a new dermatologic agent or indication requires presentation of a sufficiently large statistical data set to demonstrate the safety and efficacy of the agent for the indicated purpose(s).

9. Our June 20, 2002 Information Disclosure explains that use of imiquimod for a cosmetic dermatologic purpose is considered to be an "off FDA label use" (*i.e.*, an indication not approved by the FDA).

10. Before conducting a clinical trial on patients at facilities of the University of Miami, including for purposes of investigating a new, cosmetic use of imiquimod which could



later be used in support of an FDA submission, approval must be obtained from the University's Institutional Review Board ("IRB").

11. Beginning in November 2002 and during the winter of 2003, Dr. Welsh and I worked with the University to prepare and revise a protocol to study cosmetic use of imiquimod to reduce fine lines and clinical wrinkles for approval by the IRB. Based on the version of the protocol revised as of April 10, 2003, IRB approval was given for a one-year study entitled "Pilot Study for the Use of Aldara™ (Imiquimod 5%) for the Treatment of Photoaging" for the period August 4, 2003 to August 3, 2004. As reflected in the title, the primary objectives of this study were to further evaluate the efficacy and safety of imiquimod for the treatment of photodamaged skin.

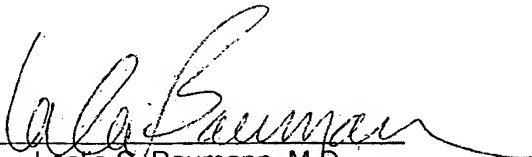
12. On May 12, 2003, the University of Miami released rights to the invention now claimed in the US Patent Application Serial No. 10/627,994.

13. The foregoing statements are made of my own knowledge and are true.

I have been warned that willful false statements and the like are punishable by fine or imprisonment, or both, and that such statements may jeopardize the validity of the application or any patent issuing thereon.

Further Declarant says not.

Dated: November 20 2007

  
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Leslie S. Baumann, M.D.

Sworn to and subscribed before  
me on this 26 day of November 2007.

